UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,619	02/27/2004	Chang Yi Wang	1151-4165US1	9919

27123 7590 01/19/2006

MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,619	WANG, CHANG YI	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-84* is/are pending in the application.

4a) Of the above claim(s) *53,55,64,66,75 and 77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52,54,56-63,67-74,76 and 78-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/27/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Applicant's Arguments Regarding Election of Species

1. Applicant response to the election of species filed September 21, 2005 is acknowledged. Applicant's election with traverse is as follows:

Elected species of immunogen formula $(A)_n$- $(Th)_m$-$(B)_o$-*(FAFSD peptide)-X,*

Elected species for *A= any amino acid, n=0.*

Elected species for *FAFSD peptide is SEQ ID: NO:8.*

Elected a species for *B is Gly-Gly, o=2*

Elected species for *Th is SEQ ID NO:49 m=1.*

Elected species for *X is* α*-COOH.*

The traversal is on the grounds that Applicant is entitled to a reasonable number of species disclosed in an application in accordance with 37 C.F.R. 1.146 and that there would be no undue burden on the Examiner to conduct a substantive examination of the claims as related to the embodiments disclosed in the instant application.

Applicant's arguments have been fully considered but they are not persuasive. The traversal is on the grounds that the examination of the entire application does not constitute a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below:

First, regarding the species election, peptides, immunogens and mimetopes have acquired a separate status in the art because of their recognized divergent subject matter and require different burdens of search.

Second, the MPEP at section 803.02 states:

An applications containing "a Markush-type" claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound "X-R", wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, "XA,XB, XC, XD, or XE". The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. A second action on the rejected claims can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a).

Thus, the MPEP teaches that election of species in Markush-type claims is permitted.

In view of al the above, for these reasons the restriction requirement is deemed to be proper and is therefore made FINAL. Claims 53, 55, 64, 66, 75 and 77 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. Claims 52, 54, 56-63, 65, 67-74, 76 and 78-84 are under examination.

Claim Objection

2. The specification is objected to because of the following informalities: Claim 52 recites "anti-FAFSD peptide which should be changed to "anti- FimH Adhesin Functional Site-Derived in the first occurrence in the claims. Correction is required.

Sequence Compliance

3. The specification is objected to because it contains sequences that are not identified in the Brief Description of the Drawings section of the specification or on the actual Figures. See the Drawings, Figure 1 in particular. Appropriate sequence identifiers should be used to comply with sequence rules. The sequences in the specification should match the paper copy of the sequence listing and computer readable form (CRF) submitted with the application. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

4. Claims 52, 54, 56-63, 65, 67-74, 76 and 78-84 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 52, 54 and 56-62 are drawn to a method for inducing anti-FAFSD peptide antibody production in a mammal by administering to said mammal a pharmaceutical composition comprising an immunologically effective amount in the range of 0.25 μg to 1mg per kilogram body weight per dose of a peptide immunogen comprising a carrier protein covalently attached to a FAFSD target selected from the group consisting of SEQ ID NO: 8 (elected sequence for the FAFSD peptide).

Claims 63, 65, 67-74, 76 and 78-84 are drawn to a method for reducing adherence to the urinary tract mucosa of a mammal by type 1 fimbriated uropathogenic enterobacteriae to prevent urinary tract infection by administering to said mammal a pharmaceutical composition comprising an immunologically effective amount in the range of 0.25 μg to 1mg per kilogram body weight per dose of a peptide immunogen comprising a carrier protein covalently attached to a FAFSD target selected from the group consisting of SEQ ID NO: 8 (elected sequence for the FAFSD peptide).

The claims are drawn to method of using a vast genus of peptide immunogens . To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus. This description would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

To adequately describe the genus of peptide immunogens one must describe determinants that would induce antibody production in a mammal. The specification has not provided written description for the elected target peptide immunogen formula:

$(A)_n$- $(Th)_m$-$(B)_o$-(FAFSD peptide)-X

Elected species for *A= any amino acid, n=0.*

Elected species for *FAFSD peptide is SEQ ID: NO:8.*

Elected a species for *B is Gly-Gly, o=2*

Elected species for *Th is SEQ ID NO:49 m=1.*

Elected species for *X is* α*-COOH.*

The instant specification has not provided a target peptide immunogen used in the claimed method that has the above elected structure. The specification has not provided a target peptide immunogen that comprise the elected FAFSD peptide SEQ ID NO:8. The amino acid sequence as set forth in SEQ ID NO:8 is

CILRQTNNYNSDDFQFVL (specification at page 10, sequence listing). The specification discloses SEQ ID NOs: 84 and 85 which comprise the elected peptide immunogen formula, but do not comprise the entire amino acid sequence as set forth in elected sequence SEQ ID NO:8 (as disclose by the sequence listing on page 10). The leucine at position 18 of SEQ ID No:8 appears to be substituted with a cysteine in the peptide immunogens set forth in SEQ ID NOs. 84 and 85. It should be noted that the instant specification discloses on page 15, paragraph 0036, Table 3 and page 31, paragraph 006, Table 5 that SEQ ID NO:8 is set forth as CILRQTNNYNSDDFQFVC. There is a discrepancy as to which amino acid sequence is SEQ ID NO:8. Thus, the specification has failed to disclose a peptide immunogen comprising the elected sequence as set forth in SEQ ID NO:8 such that the specification might reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the

written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. *The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001)* state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Therefore, absent a detailed and particular description of the elected peptide immunogen, the skilled artisan could not immediately recognize or distinguish members of the genus that would provide for a peptide immunogen that is used in the claimed method for inducing anti-FAFSD peptide antibody production in a mammal. Thus, the skilled artisan would not recognize that Applicant was in possession of the genus of peptide immunogens used in the claimed methods.

In view of the above, the instant specification fails to meet the written description as set forth under 35 U.S.C.112, first paragraph in regards to the genus of target peptide immunogens comprising SEQ ID NO:8 that are used in the claimed methods for inducing anti-FAFSD peptide antibody and reducing adherence to the urinary tract mucosa of a mammal.

Status of Claims

5. No claims are allowed.

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
December 20, 2005

MARK NAVARRO
PRIMARY EXAMINER